IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

UNITED STATES OF AMERICA, ET AL. EX REL. DR. JESSE POLANSKY, Plaintiff, -v.- PFIZER, INC., Defendant.	No. 04 CV 0704 (ERK) (ALC) ECF Case Original Filed By ECF

MEMORANDUM OF LAW IN SUPPORT OF DEFENDANT'S MOTION TO DISMISS COUNTS I AND III THROUGH XIX OF THE FIFTH AMENDED COMPLAINT

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES AND RULES

OTHER

Defendant Pfizer Inc ("Pfizer") respectfully submits this memorandum in support of its motion to dismiss, pursuant to Rules 12(b)(6) and 9(b) of the Federal Rules of Civil Procedure, Plaintiff's claims under the Federal False Claims Act and various state law false claims provisions (Counts I and III through XIX) in his Fifth Amended Complaint.

PRELIMINARY STATEMENT

By Memorandum and Order dated May 22, 2009 [Docket No. 60], this Court dismissed, with leave to replead, Plaintiff-Relator Dr. Jesse Polansky's claims under the False Claims Act ("FCA") and related state law causes of action (collectively, the "false claims counts").[1] *See United States ex rel. Polansky v. Pfizer, Inc.*, No. 04-cv-0704, 2009 WL 1456582, at *11 (E.D.N.Y. May 22, 2009) (Korman, J.) (the "May 2009 Order"). In analyzing and dismissing Plaintiff's claims under Rule 9(b), the Court both identified numerous fundamental defects in the Fourth Amended Complaint – including the absence of any allegation of an actual "false claim" for Lipitor (as defined by Plaintiff) that was submitted to the government for payment – and emphasized "the tenuous theory underlying [Plaintiff's] FCA cause of action." *Id.* at *9-10; *see also id.* at *8 (finding that "the tenuous nature of the cause of action provides all the more justification for a strict application of Rule 9(b)"). As demonstrated in detail below, the same pleading deficiencies persist in Plaintiff's Fifth Amended Complaint ("FAC") and require dismissal of his false claims counts, with prejudice, under Rule 9(b).

In addition, and as a threshold matter, a June 2009 revision of the Lipitor label, pursuant to approval by the Food and Drug Administration ("FDA") – a development of which the Court

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[1] By separate opinion filed the same day, the Court denied Pfizer's motion to dismiss Plaintiff's claims pursuant to the FCA Retaliation provision (Count II) and the New York Whistleblower Statute (Count XXII) on the ground that it was unnecessary to resolve those claims because Pfizer had not moved to dismiss Plaintiff's claims under Title VII, the New York State Human Rights Law, and New York City Human Rights Law. (*See* Memorandum & Order dated May 22, 2009 [Docket No. 61].)

may take judicial notice and one that Plaintiff conspicuously fails to even acknowledge in his amended pleading – confirms that Plaintiff's underlying theory of "off-label" promotion and FCA liability is not merely tenuous; it is completely irreconcilable with Lipitor's FDA-approved label and requires dismissal of his false claims counts as a matter of law.

As this Court observed in its May 2009 Order, Plaintiff's false claims counts are premised on his contention that the recommendations set forth in the National Cholesterol Education Program ("NCEP") Guidelines, and specifically, the LDL cholesterol levels (or "cutpoints") at which the Guidelines recommend statin therapy, limit Lipitor's FDA-approved uses or indications. (*See, e.g.*, FAC ¶¶ 7, 101-116.) May 2009 Order, 2009 WL 1456582, at *1-2. In the FAC, as in its predecessor, "Polansky alleges that promoting Lipitor therapy for patients outside [the Guidelines'] risk categories and cutpoints constitutes unlawful off-label promotion and, as such, off-label uses did not qualify for reimbursement under any federally-funded health care program." May 2009 Order, 2009 WL 1456582, at *2. (*See, e.g.*, FAC ¶¶ 101-04.) Plaintiff's theory of liability under the FCA relies entirely on a reference to the NCEP Guidelines that appeared in the "Indications and Usage" section of the Lipitor label, following the enumerated approved uses. *See* May 2009 Order, 2009 WL 1456582, at *2. (FAC ¶¶ 101, 104.)

In June 2009, the FDA approved a revised Lipitor label under regulations known as the "Physician Labeling Rule" (or the "PLR") that the Agency adopted in 2006 to streamline prescription drug labeling. *See* Final Rule, Requirements on Content & Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified as 21 C.F.R. § 201.57(c)(6) (2010)). One of the revisions to the Lipitor label pursuant to the PLR was the *removal* of the reference to the NCEP Guidelines and the accompanying summary

table on which Plaintiff continues to hang his false claims counts. (*See* Ex. A, June 2009 Lipitor Prescribing Information.)[2] This revision is not Lipitor-specific; the same change has been made to the labels of other statins as part of similar labeling updates pursuant to the PLR.[3]

This revision to the Lipitor label, made in connection with the Agency's mandate to clarify prescribing information for doctors – and not as part of an application or approval for a new indication – completely nullifies Plaintiff's central allegation that certain recommendations contained in the NCEP Guidelines restrict Lipitor's approval for treating patients with elevated LDL cholesterol. Indeed, the FDA-approved Lipitor label now directly refutes Plaintiff's allegation that a prescription for Lipitor that falls outside the cutpoint recommendations in the Guidelines is "off-label." Nor can Plaintiff now argue that any such prescription submitted to the government for payment is a "false claim." Accordingly, Plaintiff has not stated, and cannot state, a cognizable claim under the FCA or related state statutes.[4]

In sum, although Plaintiff proceeds as if it does not exist, the current Lipitor label makes it crystal clear that his FCA action amounts to nothing more than an ill-conceived attempt to second-guess the medical judgment of doctors across the country, displace the regulatory role of the FDA, and obtain a substantial monetary recovery under a factually implausible, medically unsupportable, and legally untenable theory of liability. As this is Plaintiff's Fifth Amended Complaint, his false claims counts should be dismissed with prejudice.

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2 The Exhibit is attached to the accompanying Declaration of Mark S. Cheffo.

3 *See, e.g.*, Zocor Prescribing Information, *available at* http://www.merck.com/product/usa/pi_circulars/z/zocor/zocor_pi.pdf (last visited June 17, 2010); Crestor Prescribing Information, *available at* http://www1.astrazeneca-us.com/pi/crestor.pdf (last visited June 17, 2010).

4 Although Plaintiff's entire theory of alleged "off-label" promotion of Lipitor fails as a matter of law, as set forth herein, Pfizer disputes Plaintiff's allegations and does not concede that any statement or activity by Pfizer was inconsistent with the Guidelines or false or misleading in any way.

RELEVANT FACTS

For purposes of this motion, Pfizer incorporates by reference this Court's summary of Plaintiff's allegations in its May 2009 Order and provides the following additional relevant facts.

A. Plaintiff's Fifth Amended Complaint

Plaintiff filed his Fifth Amended Complaint on February 10, 2010, six years after he first filed his original qui tam Complaint under seal and more than two years after the government completed its investigation of Plaintiff's claims that Pfizer engaged in off-label promotion of Lipitor and declined to intervene. Although Plaintiff has added certain allegations to his latest pleading, and modified others, his underlying theory of FCA liability remains the same. Plaintiff continues to charge that "Pfizer pursued an off-label marketing scheme that caused federal and state health programs to pay false or fraudulent claims for reimbursement for prescriptions of Lipitor other than those indicated on its label." May 2009 Order, 2009 WL 1456582 at *1. (*See, e.g.*, FAC ¶¶ 3-7.) In particular, Plaintiff alleges that because "Lipitor's FDA-approved labeling specifically incorporates the [NCEP] Guidelines into the prescribing information," (FAC ¶ 102), the Guidelines "provide the basis for [FDA]-approved indications for the treatment of persons with elevated levels of [LDL cholesterol]," (*id.* ¶ 3), and "promoting Lipitor therapy for patients outside" the NCEP Guidelines constitutes "unlawful off-label promotion." (*Id.* ¶ 102.) *See also* May 2009 Order, 2009 WL 1456582, at *5 ("The essence of his claim is that Pfizer advocated that Lipitor be prescribed in cases in which its use was not recommended by the Guidelines."). As in his prior pleading, Plaintiff alleges that Pfizer's promotional statements and activities for Lipitor "blur[red] the distinction between goals and cutpoints and encouraged the onset of drug therapy among moderate risk patients at thirty LDL cholesterol points below the level recommended by the Guidelines." *Id.* at *2. (*See, e.g.*, FAC ¶¶ 139-46.)

Although Plaintiff purports to identify in the FAC certain *patients* who were allegedly prescribed Lipitor "off-label," under Plaintiff's definition, (*see, e.g.*, FAC ¶¶ 415, 416), Plaintiff still does not actually identify a single "false claim" for Lipitor. He has not alleged, for example, for any purported "off-label" patient (or what he erroneously refers to as "Individual Claims," (*id.* ¶¶ 415, 416, 426)), that the patient was prescribed Lipitor as a result of his or her doctor's receiving or viewing an "off-label" statement from Pfizer; the date that any "off-label" prescription for Lipitor for the patient was submitted to the government for payment; the person or entity that submitted any such prescription; or the amount of any claim to or payment by the government for such a prescription.

Nor does Plaintiff allege any facts that would establish that the patient even fell into Plaintiff's "off-label" (or "moderate risk") category at the time he or she was first prescribed Lipitor. In other words, for example, although Plaintiff cites information about the cholesterol levels and risk factors of two patients allegedly identified from data collected as part of the National Health and Nutrition Examination Survey ("NHANES"), Plaintiff alleges only that the patients were "taking Lipitor" and that their LDL levels were below the 160 mg/dL "cutpoint" on which he bases his "off-label" allegation. (FAC ¶¶ 415, 416.) Cholesterol levels, of course, are not static, and Plaintiff fails to allege, among other critical information, the patients' LDL level at the time they were first prescribed Lipitor or whether the patients had previously been prescribed and taken another statin to treat elevated cholesterol.

B. The 2009 Lipitor Label

Plaintiff's entire theory of "off-label" promotion and FCA liability relies on a reference to the NCEP Guidelines that has been removed from the Lipitor label. In June 2009, the FDA

approved the current label for Lipitor.[5] As noted above, that label reflects revisions undertaken pursuant to the Physician Labeling Rule or "PLR," the FDA's 2006 amendments to its regulations governing the content and format of prescription drug labeling. *See* Final Rule, Requirements on Content & Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (codified as 21 C.F.R. § 201.57(c)(6)). In a preamble to the final PLR, the FDA set forth the following background and objectives of its amended labeling regulations, which it had previously issued for comment as a "Proposed Rule":

> In recent years, there has been an increase in the length, detail, and complexity of prescription drug labeling, making it harder for health care practitioners to find specific information and to discern the most critical information.
>
> The agency's proposed changes were designed to enhance the ability of health care practitioners to access, read, and use prescription drug labeling.

Id. at 3922-23. Among other changes, the revised labeling regulations require manufacturers of prescription medicines to add an introductory "Highlights" section and to reorder and reorganize prescribing information "to make the labeling easier to use and read." *Id.* at 3923.

As amended and approved by the FDA pursuant to the PLR, the June 2009 Lipitor label includes an "Indications and Usage" section under both the introductory "Highlights" and in the "Full Prescribing Information." (*See* Ex. A, June 2009 Lipitor Label at 1-2.) Neither section refers or cites to the NCEP Guidelines or the purported LDL "cutpoints" for statin therapy on which Plaintiff's theory of false claims liability relies. Instead, both sections list Lipitor's FDA-approved indications as an adjunct to diet for the treatment of hyperlipidemia (high cholesterol) and the prevention of cardiovascular disease in various patient populations. (*See id.*) For example, the Full Prescribing Information sets forth the following indications for hyperlipidemia:

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[5] *See* Lipitor Label and Approval History, at http://www.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm?fuseaction=Search.Label_ApprovalHistory#apphist (last visited June 17, 2010).

> 1.2 Hyperlipidemia
>
> LIPITOR is indicated:
>
> • As an adjunct to diet to reduce elevated total-C, LDL-C, apo B, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia (Fredrickson Types IIa and IIb);
>
> • As an adjunct to diet for the treatment of patients with elevated serum TG levels (Fredrickson Type IV);
>
> • For the treatment of patients with primary dysbetalipoproteinemia (Fredrickson Type III) who do not respond adequately to diet;
>
> • To reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable;
>
> • As an adjunct to diet to reduce total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present:
>
> a. LDL-C remains ≥ 190 mg/dL or
>
> b. LDL-C remains ≥ 160 mg/dL and:
>
> - there is a positive family history of premature cardiovascular disease or
> - two or more other CVD risk factors are present in the pediatric patient

(*Id.* at 2.) In addition, the "Indications and Usage" sections identify the following "Limitations of Use": "LIPITOR has not been studied in conditions where the major lipoprotein abnormality is elevation of chylomicrons (*Fredrickson* Types I and V)."[6] (*Id.* at 2 (Part 1.3).) There is no reference, under "Limitations of Use," to the NCEP Guidelines or to the LDL "cutpoints" that Plaintiff alleges constrain Lipitor's approved uses.

As indicated in the portion of the label quoted above, the "Indications and Usage" section of the Lipitor label *does* continue to include a series of LDL thresholds for use in

[6] Like LDL and HDL, chylomicrons are a type of lipoprotein.

children between the ages of 10 and 17. Specifically, for that category of patients, Lipitor is approved as an adjunct to diet to reduce elevated cholesterol if "the following findings are present: a. LDL-C remains ≥ 190 mg/dL or b. LDL-C remains ≥ 160 mg /dL and [other specified conditions exist]." (*Id.* at 2.) Lipitor's FDA-approved indications do not include any other LDL thresholds. Thus, to show off-label promotion, Plaintiff ironically alleges that Pfizer promoted Lipitor in a manner that is inconsistent with information *not* included on the label.

ARGUMENT

I. LEGAL STANDARDS

A Rule 12(b)(6) motion should be granted where a plaintiff is unable to delineate "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007). In *Ashcroft v. Iqbal*, 129 S. Ct. 1937 (2009), the Supreme Court underscored that "[t]he plausibility standard . . . asks for more than a sheer possibility that a defendant has acted unlawfully." *Id.* at 1949. Rather, a district court "'retain[s] the power to insist upon some specificity in pleading before allowing a potentially massive factual controversy to proceed.'" *Twombly*, 550 U.S. at 558 (citation omitted); *accord Iqbal*, 129 S. Ct. at 1950 (Rule 8 "does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions"). In assessing the adequacy of a claim and weighing competing inferences of lawful and unlawful conduct, courts must rely upon "judicial experience and common sense." *Iqbal*, 127 S. Ct. at 1950.

The Supreme Court has further advanced a "two-pronged approach," which this Court has followed, to assessing the adequacy of a complaint under Rule 8. *Willets Point Indus. & Realty Ass'n v. City of New York*, No. 08-cv-1453, 2009 WL 4282017, at *3 (E.D.N.Y. Nov. 25, 2009) (Korman, J.) ("*Willets Point*") (citing *Iqbal*, 127 S. Ct. at 1950). First, "the motion to dismiss analysis begins with the 'identif[ication of] the allegations in the complaint that are not

entitled to the assumption of truth.'" *Willets Point*, 2009 WL 4282017, at *5 (finding that "[m]any of plaintiffs' allegations in support of their [equal protection] cause of action [were] nothing more than 'bare assertions' amounting to a 'formulaic recitation of the elements of a . . . [class-of-one equal protection] claim'" (quoting *Iqbal*, 127 S. Ct. at 1951)). Second, the court should "discern whether the remaining well-pled factual allegations 'plausibly suggest an entitlement to relief.'" *Id.* (quoting *Iqbal*, 127 S. Ct. at 1951). Factual allegations will not satisfy the plausibility test where, as the Court found in *Willets Point*, there are "more likely explanations" or "'obvious alternative explanations'" for the alleged conduct or harm. *Id.* at *6 (citing cost-benefit analysis conducted by the City of New York and differences in the residential nature of various Queens neighborhoods as "more likely explanations" for the City's decision to make larger investments in the infrastructure in other neighborhoods than in Willets Point).

In addition to meeting the Rule 8 pleading standards set forth in *Twombly* and *Iqbal*, Plaintiff's False Claims Act counts must, as this Court has held, satisfy Rule 9(b) "because the FCA is an anti-fraud statute." May 2009 Order, 2009 WL 1456582, at *4 (citing *Gold v. Morrison-Knudsen Co.*, 68 F.3d 1475, 1476 (2d Cir. 1995) (per curiam)). Rule 9(b) requires a plaintiff to state the circumstances constituting fraud with particularity, which means a plaintiff must "'(1) specify the statements that the plaintiff contends were fraudulent; (2) identify the speaker; (3) state where and when the statements were made; and (4) explain why the statements were fraudulent.'" May 2009 Order, 2009 WL 1456582, at *4 (quoting *Rombach v. Chang*, 355 F.3d 164, 170 (2d Cir. 2004)). The facts alleged in support of a fraud claim must "'strengthen the inference of fraud beyond possibility.'" *Id.* at *10 (quoting *United States ex rel Rost v. Pfizer, Inc.*, 507 F.3d 720, 733 (1st Cir. 2007)); *accord Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1128 (2d Cir. 1994). As the Second Circuit has explained, "[t]his pleading constraint serves to

provide a defendant with fair notice of a plaintiff's claim, safeguard his reputation from improvident charges of wrongdoing, and protect him against strike suits." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 99 (2d Cir. 2007).

II. PLAINTIFF'S FALSE CLAIMS COUNTS FAIL AS A MATTER OF LAW BECAUSE THEY CONFLICT DIRECTLY WITH THE LIPITOR LABEL

As set forth in Part III below, the same lack of specificity that this Court held required dismissal of the false claims counts in Plaintiff's Fourth Amended Complaint mandates their dismissal, with prejudice, in his amended pleading. However, the FDA-approved Lipitor label itself – the basis for Plaintiff's entire theory of liability – now makes it clear that the Court need not even reach Plaintiff's Rule 9(b) deficiencies. Specifically, a plain reading of the Lipitor label confirms that Plaintiff's underlying theory – that the NCEP Guidelines restrict Lipitor's FDA-approved indications for the treatment of persons with elevated LDL cholesterol – fails on its face to state a plausible claim for relief.

As this Court has noted, the False Claims Act is a fraud prevention statute. *See* May 2009 Order, 2009 WL 1456582, at *10. It prohibits efforts to "extract[] money the government otherwise would not have paid." *Mikes v. Straus,* 274 F.3d 687, 696 (2d Cir. 2001). Thus, to be liable under the FCA, a defendant must have submitted, or caused to be submitted, a claim that it knew to be false. *See* 31 U.S.C. § 3729(a)(1)-(2). A complaint filed under the FCA must, therefore, allege facts sufficient to establish that a claim submitted to the government for payment contained a conscious and deliberate "lie." *Wang v. FMC Corp.*, 975 F.2d 1412, 1421 (9th Cir. 1992); *see also United States ex rel. Lamers v. City of Green Bay*, 168 F.3d 1013, 1020 (7th Cir. 1999) ("[V]iolations of . . . regulations are not fraud unless the violator knowingly lies to the government about them."); *accord Mikes*, 274 F.3d at 703.

This Court has already recognized that this case bears no resemblance to the typical FCA action involving patently obvious falsehoods. *See* May 2009 Order, 2009 WL 1456582, at *8. Even before the FDA approved the current Lipitor label, which deleted the language on which Plaintiff's entire case, and the Court's May 2009 Order relied, the Court observed:

> [T]he facts in this case are the opposite of the "archetypal *qui tam* FCA action," which is "filed by an insider at a private company who discovers his employer has overcharged under a government contract." They also bear no resemblance to other FCA actions that have been sustained "under theories of supplying substandard products or services; false negotiation, including bid rigging and defective pricing; and false certification."

Id. (quoting *United States ex rel. Hopper v. Anton*, 91 F.3d 1261, 1266 (9th Cir. 1996)). Among other problems with Plaintiff's underlying theory, this Court noted that, in contrast to the objective lies implicated by claims submitted to the government in the foregoing FCA cases, a claim for payment for a Lipitor prescription – one that presumably (and Plaintiff does not allege otherwise) accurately and truthfully identifies the patient, his or her condition, and the treatment (the prescription of Lipitor) – cannot be literally false. 2009 WL 1456582, at *6-8. The Court cited the "tenuous nature" of a FCA action involving truthful (rather than patently false) claims for "off-label" Lipitor prescriptions in support of its strict application of Rule 9(b). *Id.* at *8.

The Court's analysis applies with even greater force to Plaintiff's amended pleading, and, indeed, supports a finding that Plaintiff's cause of action is no longer even tenuous; it is facially implausible. As established above, the current Lipitor label, which, pursuant to the FDA's 2006 amended labeling regulations, represents a clarification of Lipitor's approved indications and other prescribing information, does not include the reference to the NCEP Guidelines or the Guidelines summary table (Table 6), on which Plaintiff continues to attempt to anchor his false claims counts. Rather, the label confirms that Lipitor is approved as an adjunct to diet in the

treatment of elevated cholesterol, without restriction to the Guidelines' recommended "cutpoints."[7]

As Plaintiff acknowledges, the federal government provides for payment for prescriptions medications under Medicare and Medicaid as long as the prescription is for a "medically accepted indication," 42 U.S.C. § 1396r-8(d)(1)(B)(i), which includes uses approved by the FDA. *See* 42 U.S.C. §§ 1395w-102(e), 1396r-8(k)(6), 1396r-8(g)(1)(B)(i). (FAC ¶¶ 38-39, 54-55, 80.) Thus, because elevated cholesterol is a "medically accepted indication" for Lipitor under the relevant statutes, and therefore one that the government is required to cover, a claim for a prescription for Lipitor cannot be "false" merely because it falls outside the NCEP Guidelines' "cutpoints." This simple fact is fatal to Plaintiff's false claims counts.

Even if the revised Lipitor label did not unequivocally negate Plaintiff's theory of "fraudulent" conduct – that is, Pfizer's alleged promotion of Lipitor outside the NCEP Guidelines – that theory could not sustain his false claims counts because it involves a subjective view of how, if at all, the NCEP Guidelines restrict Lipitor's approved uses. It is well settled that "differences in interpretation growing out of a disputed legal question are . . . not false under the FCA." *Lamers*, 168 F.3d at 1018; *accord United States ex rel. Wilson v. Kellogg Brown & Root, Inc.*, 525 F.3d 370, 377 (4th Cir. 2008); *see also United States ex rel. Roby v. Boeing Co.*, 100 F. Supp. 2d 619, 625 (S.D. Ohio 2000) (noting that "[e]xpressions of opinion, scientific

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[7] The Guidelines themselves further refute Plaintiff's contention that they restrict Lipitor's FDA-approved indications. According to the Guidelines, the ATP-III Report "should not be viewed as a standard of practice" and the "recommendations" it sets out "represent general guidance that can assist in shaping clinical decisions" but "should not override a clinician's considered judgment in the management of individuals." National Cholesterol Education Program, Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III) (September 2002), *available at* http://www.nhlbi.nih.gov/guidelines/cholesterol/atp3full.pdf, at I-2. Thus, by their plain language, the Guidelines represent recommendations that physicians may take into account in determining whether to prescribe a statin for one of its indicated uses, but they are not part of the indicated uses themselves.

judgments, or statements as to conclusions about which reasonable minds may differ" are not actionable under the FCA), *aff'd*, 302 F.3d 637 (6th Cir. 2002). FCA claims must be dismissed where, as here, they "rest[] not on any objective falsehood, as required by the FCA, but rather on [plaintiff's] subjective interpretation" of defendant's legal duties. *Wilson*, 525 F.3d at 377; *accord United States ex rel. Morton v. A Plus Benefits, Inc.*, 139 F. App'x 980, 984 (10th Cir. 2005) (dismissing FCA claims predicated on violation of ambiguous terms of ERISA plan).

In sum, because Plaintiff does not allege that Pfizer promoted Lipitor for any purpose other than the approved use of lowering cholesterol in patients with elevated cholesterol levels, much less that Pfizer caused the submission of any non-reimbursable claim for Lipitor, he has not stated a plausible claim under the False Claims Act or related state laws and his claims should be dismissed under Rule 12(b)(6).

III. PLAINTIFF'S FALSE CLAIMS COUNTS DO NOT SATISFY RULE 9(b)

Even if Plaintiff's amended false claims counts did not fail as a matter of law based on the Lipitor label, they should be dismissed under Rule 9(b) for failure to plead fraud with particularity. Plaintiff's litany of allegations of purportedly improper promotional statements and activities remains a grossly inadequate substitute for facts plausibly establishing that any such statement or activity actually caused a doctor or pharmacist to submit a false or non-reimbursable claim for Lipitor to the government for payment. Although Plaintiff has added certain allegations about Pfizer's purported "off-label" marketing scheme, and identified a small number of patients whom he claims were prescribed Lipitor "off-label," when it comes to the elements actually necessary to maintain a FCA action, including the identification of actual false claims, his amended pleading remains entirely speculative and conclusory.

A. The Complaint Fails to Allege that Pfizer Caused the Submission or Approval of a False Claim

As this Court observed, to pursue a cause of action under the FCA, Plaintiff must allege that Pfizer "knowingly present[ed], or cause[d] to be presented, to an officer or employee of the United States government . . . a false or fraudulent claim for payment or approval," 31 U.S.C. § 3729(a)(1), or that Pfizer "knowingly [made], use[d], or cause[d] to be made or used, a false record or statement to get a false or fraudulent claim" paid or approved by the Government. *Id.* § 3729(a)(2); *see also* May 2009 Order, 2009 WL 1456582, at *3.[8] This Court has recognized that to satisfy Rule 9(b)'s "'who, what, when, where and how'" requirements in a FCA action,

> a relator must provide details that identify particular false claims for payment that were submitted to the government. In a case such as this, details concerning the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government, the particular goods or services for which the government was billed, the individuals involved in the billing, and the length of time between the alleged fraudulent practices and the submission of claims based on those practices are the types of information that may help a relator to state his or her claims with particularity. These details do not constitute a checklist of mandatory requirements that must be satisfied by each allegation included in a complaint. However, . . . some of this information for at least some of the claims must be pleaded in order to satisfy Rule 9(b).

Id. at *4 (quoting *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232-33 (1st Cir. 2004) (internal citations and quotations omitted)). Similarly, another district court addressing FCA claims that were premised, like Plaintiff's, on alleged off-label promotion of prescription medicines, explained:

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[8] The recent amendments to the FCA by the Fraud Enforcement Recovery Act of 2009, Pub L. No. 111-21, § 4(a)(1), 123 Stat. 1617, 1621 (May 20, 2009), are inapplicable here because, by their terms, the amendments apply only to conduct occurring after May 20, 2009, or, in the case of the amendments to section 3729(a)(2), only to claims (not cases) pending on or after June 7, 2008. *See Id.* § 4(f)(1), 123 Stat. at 1626; *see also Hopper v. Solvay Pharmaceuticals, Inc.* 588 F.3d 1318, 1327 (11th Cir. 2009) ("We interpret the word 'claim' in section 4(f) to mean 'any request or demand . . . for money or property,' as defined by 31 U.S.C. § 3729(b)(2)(A) (as amended May 2009)."); *accord United States ex rel. Sanders v. Allison Engine Co.*, 667 F. Supp. 2d 747, 752 (S.D. Ohio 2009) ("[A] plain reading of the retroactivity language reveals that the relevant change is applicable to 'claims' and not to 'cases.'").

> To meet Rule 9(b)'s heightened pleading for a claim under § 3729(a)(1), [plaintiff] must identify specific false claims for payment as well as (1) who submitted the false claim, (2) what the person submitted, (3) when he submitted the claim, (4) where he did so and (5) how he did so. He must also plead how Defendants caused the claim to be submitted. [Plaintiff's] § 3729(a)(2) claim requires him to identify particular false records or false statements that Defendants made in order to get the government to pay money.

United States ex rel. West v. Ortho-McNeil Pharm., Inc., No. 03 C 8239, 2007 WL 2091185, at *3 (N.D. Ill. July 20, 2007) (citation omitted). Like the relator in *West*, Plaintiff does not even come close to satisfying these standards.

As this Court and others have emphasized, "a relator cannot circumscribe the Rule 9(b) pleading requirements by alleging a fraudulent scheme in detail and concluding, that as a result of the fraudulent scheme, false claims must have been submitted. Rather, actual false and fraudulent claims are 'the *sine qua non* of a False Claims Act litigation.'" May 2009 Order, 2009 WL 1456582, at *5 (quoting *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d 1301, 1311 (11th Cir. 2002) (additional citations omitted); *accord Hopper v. Solvay Pharma., Inc.*, 588 F.3d 1318, 1328 (11th Cir. 2009)) ("Improper practices standing alone are insufficient to state a claim under either § 3729(a)(1) or (a)(2) absent allegations that a specific fraudulent claim was in fact submitted to the government."); *United States ex rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 232 (1st Cir. 2004) (noting that pleadings describing alleged schemes "invariably are inadequate unless they are linked to allegations . . . of actual false claims"); *United States ex rel. Wilkins v. United Health Group, Inc.*, No. 08-3425, 2010 U.S. Dist. LEXIS 47080, at *14 (D.N.J. May 13, 2010) ("Without an allegation of a claim, Relators' False *Claims* Act claim is like a battery without a touching, or defamation without a statement. Simply put, it is not a claim for relief.").

Thus, even if Plaintiff's theory of "off-label" promotion of Lipitor were not defective on its face for the reasons set forth in Part II above, "the mere fact that Pfizer may have been

violating FDA regulations" – which Pfizer denies – "does not translate into liability for causing a false claim to be filed." May 2009 Order, 2009 WL 1456582, at *7; *see also id.* at *5 (the FCA "'attaches liability, not to the underlying fraudulent activity or to the government's wrongful payment, but to the "*claim for payment*"'" (quoting *United States v. Rivera*, 55 F.3d 703, 709 (1st Cir. 1995) (emphasis added)). Although Plaintiff has labeled several paragraphs in the FAC "Individual Claims," (FAC ¶¶ 415, 416, 426), the heading is a complete misnomer. The fact remains that he has not identified a single false claim for an "off-label" Lipitor prescription. In the absence of specific false claims, Plaintiff's Complaint, like that dismissed in *Hopper*, another FCA action premised on alleged off-label promotion, simply "piles inference upon inference" in his attempt to allege that Pfizer's "marketing campaign influenced some unknown third parties to file false claims." *Hopper*, 588 F.3d at 1326.

As noted above, Plaintiff's allegations of "Individual Claims" do not actually identify claims but instead purport to identify individuals who were prescribed Lipitor "off-label," where the "off-label" characterization is based on an alleged measurement of the individual's LDL level on some unspecified date and at some unidentified time relative to the also unidentified date that the patient was first prescribed Lipitor. (*See* FAC ¶¶ 415, 416, 426.) Plaintiff does not, however, allege how any specific statement or action by Pfizer or any Pfizer employee caused any physician to write an "off-label" prescription of Lipitor for any of these patients. For two of the patients, Plaintiff alleges that the person "was on Medicaid," (*id.* ¶¶ 415, 416), and for some of the others, he identifies a government "Payor." (*Id.* ¶ 426.) But he does not allege that any "off-label" Lipitor prescription for any of the patients was submitted to the government for payment or reimbursement. Similarly, Plaintiff does not identify, or attach any supporting documentation of, *any* of the following particulars cited by this Court for any claim for Lipitor

for any of the alleged "off-label" patients: "'the dates of the claims, the content of the forms or bills submitted, their identification numbers, the amount of money charged to the government . . . the individuals involved in the billing, [or] the length of time between the alleged fraudulent practices and the submission of claims based on those practices.'" May 2009 Order, 2009 WL 1456582, at *4 (quoting *Karvelas*, 360 F.3d at 232-33). Indeed, Plaintiff has not identified any federal funds that were expended in connection with any alleged false claim for Lipitor.

As this Court held in dismissing Plaintiff's Fourth Amended Complaint, and as the courts in *Hopper* and a multitude of similar FCA cases have held, such speculative pleading does not withstand scrutiny under Rule 9(b). *See* May 2009 Order, 2009 WL 1456582, at *5; *Hopper*, 588 F.3d at 1326 (affirming dismissal of FCA action based on alleged off-label promotion where complaint failed to allege, among other things, "dates, times, or amounts of individual false claims"); *West*, 2007 WL 2091185, at * 4 (dismissing same where, inter alia, plaintiff "[did] not identify which sales representatives made the [allegedly false statements to doctors], when they made them, to which doctors they made them or how they communicated them," and "[did] not set forth the circumstances of any particular false statement or cite a single example of a false claim"); *United States ex rel. McDermott v. Genentech, Inc.*, No. 05-147-P-C, 2006 WL 3741920, at *10-13 (D. Me. Dec. 14, 2006) (recommending dismissal of same for failure to identify specific false claims), *report and recommendation adopted*, 2007 WL 2128410 (D. Me. July 24, 2007); *United States ex rel. Hess v. Sanofi-Synthelabo, Inc.*, No. 4:05CV570, 2006 WL 1064127, at *6, *11 (E.D. Mo. Apr. 21, 2006) (dismissing similar "off-label" FCA action on same grounds).[9]

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[9] *See also Wood ex rel. United States v. Applied Research Assocs., Inc.*, 328 F. App'x 744, 750 (2d Cir. 2009) (affirming dismissal with prejudice of FCA complaint against government contractors where, inter alia, the complaint "'[did] not cite to a single identifiable record or billing submission [plaintiff] claim[ed] to be false, or *(cont'd)*

Finally, Plaintiff's allegations about a "statistical analysis of NHANES data" obtained in connection with this litigation (FAC ¶ 403), cannot serve as a proxy for the missing (and necessary) false claims.[10] Courts have repeatedly held that allegations of statistical information are insufficient to satisfy Rule 9(b) in a FCA action. *See, e.g.*, *United States ex rel. Kneepkins v. Gambro Healthcare, Inc.*, 115 F. Supp. 2d 35, 45 (D. Mass. 2000) ("[Rule 9(b)] requires greater specificity than statistical analysis."); *Hopper*, 588 F.3d at 1326 (affirming dismissal where, although the amended complaint "include[d] what the relators describe[d] as 'a highly-compelling statistical analysis [that] render[ed] inescapable the conclusion that a huge number of claims for ineffective off-label uses of Marinol resulted from [Solvay's illegal marketing] campaign,'" it did not allege "a single actual false claim" (citation omitted)). Moreover,

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give a single example of when a purportedly false claim was presented for payment by a particular defendant at a specific time'" (citation omitted)), *cert. denied*, 130 S. Ct. 1285 (2010); *United States ex rel. Sikkenga v. Regence Bluecross Blueshield of Utah*, 472 F.3d 702, 727 (10th Cir. 2006) (affirming dismissal of FCA claim because the relator's complaint "[fell] woefully short of adequately pleading that false or fraudulent claims were submitted" where the relator failed to link assertions of "wrongful activit[y]" to "'actual false claims submitted to the government'" (citation omitted)); *United States ex. rel. Karvelas v. Melrose-Wakefield Hosp.*, 360 F.3d 220, 235 (1st Cir. 2004) ("[The relator's] failure to identify with particularity any actual false claims that the defendants submitted to the government is, ultimately, fatal to his complaint."); *United States ex rel. Clausen v. Lab. Corp. of Am., Inc.*, 290 F.3d at 1301, 1312 & n.21 (11th Cir. 2002) (affirming finding that FCA complaint was defective where relator provided "[n]o copy of a single bill or payment," noting: "We cannot make assumptions about a False Claim Act defendant's submission of actual claims . . . without stripping all meaning from Rule 9(b)'s requirement of specificity or ignoring that the 'true essence of the fraud of a False Claims Act action involves an actual claim for payment and not just a preparatory scheme."); *Johnson ex rel. United States v. Univ. of Rochester Med. Ctr.*, 07-CV-6149L, 2010 U.S. Dist. LEXIS 14136, at *10 (W.D.N.Y. Feb. 18, 2010) (granting dismissal of FCA action, noting that while "plaintiffs' claims [were] set forth in a behemoth fifty-five page, 183-paragraph complaint, the majority of which [was] devoted to lengthy descriptions of" the defendant hospital's alleged fraudulent billing and medical practices, "[n]owhere in their lengthy pleading [did] the plaintiffs allege or describe how, *or even if*, any bills for procedures involving falsified records were ever presented to Medicare or Medicaid for payment"); *United States ex rel. Driscoll v. Serono Inc.*, No. 00-11680, 2008 WL 728939, at *3 (D. Mass. Mar. 18, 2008) (dismissing false claims counts under Rule 9(b) because the complaint "describe[d] an allegedly illegal 'scheme,' but only refer[ed] to specific false claims in the most conclusory terms, rather than with particularity as required by Rule 9(b)"); *United States ex rel. Serrano v. Oaks Diagnostics, Inc.*, 568 F. Supp. 2d 1136, 1142-43 (C.D. Cal. 2008) (dismissing FCA action where government simply appended a chart purporting to list over 1000 false claims but provided none of the required specifics for any of the claims).

[10] In addition to being an improper substitute for specific false claims, Plaintiff's alleged statistical support based on NHANES data suffers from the same limitations cited above in connection with Plaintiff's purported identification of specific "off-label" patients from the same data. *See supra* at p. 5.

Plaintiff's alleged statistics about the number of "Lipitor prescriptions that were filled by people who," according to Plaintiff, "did not qualify for statin therapy" because they were "off-guideline," (FAC ¶ 403), do not provide any information about reimbursement requests or claims practices, much less any of the requisite details cited by the Court as necessary to meet Rule 9(b). *See* May 2009 Order, 2009 WL 1456582, at *3.

In addition, to the extent any of Plaintiff's allegations of a massive scheme of "off-label" promotion can be read as "well-pleaded facts," they nevertheless fail the *Twombly/Iqbal* plausibility test because they do not account for an "'obvious alternative explanation[]'" for the harm alleged. *Willets Point*, 2009 WL 4282017, at *6-7. Like the lawful conduct of the City that was the "more likely explanation" for the injury alleged in *Willets Point*, *id.* at *6, the independent clinical decision-making of doctors is, as the Court has already indicated, an obvious alternative explanation for the "harm" Plaintiff claims here. *See* May 2009 Order, 2009 WL 1456582, at *10.

B. The Complaint Fails to Allege Any Legally False Claim

As this Court has recognized, to proceed under the FCA, Plaintiff must allege, in addition to all of the claim-specific details, including causation, set forth above, facts demonstrating that the claim was "legally false" because it was based on "'the false *certification* of compliance'" with a federal statute or regulation that was a condition of government payment for the claim.[11] May 2009 Order, 2009 WL 1456582, at *7 (quoting *United States ex rel. Hopper v. Anton*, 91 F. 3d 1261, 1266 (9th Cir. 1996)); *accord Wilkins*, 2010 U.S. Dist. LEXIS 47080, at *9. Here, as before, Plaintiff has not alleged facts establishing any "legally false"

[11] Plaintiff's claims do not implicate the second category of FCA violation, a "'factually false'" claim, because they do not "involve[] an incorrect description of goods or services provided or a request for reimbursement for goods or services never provided." *Mikes v. Straus*, 274 F.3d 687, 697 (2d Cir. 2001) (citation omitted).

certification of compliance by Pfizer with regard to any claim for Lipitor. As this Court explained in its May 2009 Order, under the Second Circuit's decision in *Mikes v. Straus*, 274 F.3d 687 (2d Cir. 2001):

> There are two kinds of certifications that can fall within this category. One is a claim that expressly "certifies compliance with a particular statute, regulation or contractual term, where compliance is a prerequisite to payment." No such certification is alleged to have been made here. The second category involves an *implied certification*. "An implied false certification claim is based on the notion that the act of submitting a claim for reimbursement itself implies compliance with governing federal rules that are a precondition to payment." Specifically, "implied false certification is appropriately applied only when the underlying statute or regulation upon which the plaintiff relies *expressly* states the provider must comply in order to be paid." Thus, "[l]iability under the Act may properly be found . . . when a defendant submits a claim for reimbursement while knowing – as that term is defined by the Act, *see* 31 U.S.C. § 3729(b), that payment expressly is precluded because of some noncompliance by the defendant."

May 2009 Order, 2009 WL 1456582, at *7 (first emphasis added) (quoting *Mikes*, 274 F.3d at 698-700); *accord Rodriguez v. Our Lady of Lourdes Med. Ctr*, 552 F.3d 297, 304 (3d Cir. 2008) ("To state a claim under [an implied certification] theory it is necessary to allege not only a receipt of federal funds and a failure to comply with applicable regulations, but also that payment of the federal funds was in some way conditioned on compliance with those regulations."), *overruled in part on other grounds by United States ex rel. Eisenstein v. City of New York*, 129 S. Ct. 2230 (2009). Indeed, as the Second Circuit has noted, because the FCA is "aimed at retrieving ill-begotten funds, it would be anomalous to find liability when the alleged noncompliance would not have influenced the government's decision to pay." *Mikes*, 274 F.3d at 697; *see also Allison Engine Co. v. United States ex rel. Sanders*, 553 U.S. 662, 128 S. Ct. 2123, 2126 (2008) (to plead a claim under section 3729(a)(2), a plaintiff must show "that the

defendant intended that the false statement be material to the Government's decision to pay or approve the false claim").[12]

The Court found that Plaintiff's Fourth Amended Complaint did not satisfy *Mikes'* implied certification standard because, under Plaintiff's allegations, "Pfizer did not file any claims for reimbursement and made no implied certifications to obtain payment." May 2009 Order, 2009 WL 1456582, at *7. Nothing in Plaintiff's amended pleading changes this analysis. Plaintiff continues to allege that every purported "off-label" prescription for Lipitor, no matter why it was written, how much it helped the patient who received it, or how it was submitted for payment, is a "false claim." But as the Court has observed, "off-label" *prescriptions* for Lipitor, even to the extent Plaintiff now attempts to identify some by listing alleged "off-label" patients (not individual prescriptions), "[are] not *claims* that were submitted for payment," and are not, therefore, without more, actionable false claims. *Id.* (emphasis added).

Moreover, the Court has recognized that off-label prescribing is widespread and, as the FDA has advised physicians, may be completely appropriate in certain cases. *See id.*; *see also id.* at *10 ("Significantly, as I have already observed, the FDA does not prohibit physicians, who are free to do so, from prescribing Lipitor for patients with normal cholesterol."). As the Court has observed, there are numerous reasons why a physician may have prescribed Lipitor to a "moderate risk" patient, including published studies reporting benefits in using statins to lower LDL cholesterol levels below the NCEP Guidelines' targets and to treat patients with LDL levels below the Guidelines' "cutpoints." *See id.* at *9-10. Given these facts, "the entities to which reimbursement claims are made could hardly be understood to have operated on the assumption

[12] The amendments to the FCA under the Fraud Enforcement and Recovery Act of 2009 modify *Allison Engine's* intent requirement. *See* 31 U.S.C. 3729(a)(1)(B) (recodifying former 31 U.S.C. 3729(a)(2)). As noted above, however, because this action was filed prior to the amendments and involves claims before June 7, 2008, the FERA amendments do not govern this action. *See supra* note 8.

that the physician writing the prescription was certifying implicitly that he was prescribing Lipitor in a manner consistent with the Guidelines." *Id.* at *7; *cf. United States ex rel. Phillips v. Permian Residential Care Ctr.*, 386 F. Supp. 2d 879, 884 (W.D. Tex. 2005) ("[T]he False Claims Act should not be used to call into question a health care provider's judgment regarding a specific course of treatment.").

Plaintiff has not alleged that for any of the purported "off-label" Lipitor patients he lists in paragraphs 415, 416, or 426 of the FAC, any form or statement submitted to the government for reimbursement or payment falsely reported anything about the patient's condition or the prescription of Lipitor for the patient. To the contrary, Plaintiff concedes in the FAC that any actual "claims for payment" submitted to the government for Lipitor prescriptions "*do not distinguish between on-label and off-label uses*." (FAC ¶ 34 (emphasis added).) In *United States ex rel. Hess v. Sanofi-Synthelabo*, cited above, the court found analogous circumstances dispositive with regard to claims involving Eloxatin, one of the cancer medications at issue. *See Hess*, 2006 WL 1064127, at *7. Plaintiff there alleged that defendant had promoted Eloxatin as a first-line cancer treatment when it was approved only for late-stage treatment, resulting in the submission of (unidentified) off-label claims to Medicare. *See id.* at *2, *7. The court held that because the Medicare claim form for Eloxatin did not require a doctor to indicate the stage of the patient's cancer, a fact conceded by plaintiff in his complaint, "the stage of a patient's cancer [was] not material to a doctor's seeking reimbursement for his or her prescribing Eloxatin for treatment of cancer," and, "therefore, was not material to [the Medicare payor] in making a decision to reimburse doctors for their prescription of Eloxatin." *Id.* at *7. As a result, the plaintiff could not state a FCA claim with respect to Eloxatin. *See id.* The same reasoning applies and supports dismissal here, where Plaintiff affirmatively alleges that whether or not a

prescription for Lipitor met the Guidelines' "cutpoints" is not something that doctors specify or that the government considers in connection with a claim for payment.

Thus, because the complaint fails to allege the necessary "direct link" between Pfizer's alleged conduct and the government's decision to cover any purported false claim, Plaintiff's allegations are "too attenuated to establish liability." *Allison Engine*, 128 S. Ct. at 2130; *see also Hopper*, 588 F.3d at 1330-31 (affirming dismissal where plaintiff "[did] not allege that Solvay intended its false statements to play any role in the government's decision to reimburse state health programs for the cost of [the] prescriptions," noting: "We cannot infer that because Solvay allegedly intended its marketing campaign to convince physicians to write off-label prescriptions, Solvay intended for that campaign to influence the government's decision to pay for those prescriptions.").[13]

IV. PLAINTIFF SHOULD NOT BE PERMITTED TO AMEND HIS FALSE CLAIMS COUNTS

This Court has already considered and, consistent with a long line of authority, properly rejected Plaintiff's request that the Court relax Rule 9(b)'s requirements or permit Plaintiff to conduct discovery to try to meet his pleading burden. *See, e.g.*, May 2009 Order, 2009 WL 1456582, at *10 ("Most courts do not permit parties to conduct discovery in order to satisfy the requirements of Rule 9(b)." (citing cases)). Plaintiff has now had yet another opportunity to amend his Complaint, this time with the benefit of specific guidance from the Court. Yet even

[13] Consistent with this Court's decision dismissing all of Plaintiff's false claims counts in his Fourth Amended Complaint, Plaintiff's state law claims should be dismissed along with this federal FCA count for all of the reasons set forth above. *See United States ex rel. Rost v. Pfizer Inc.*, 446 F. Supp. 2d 6, 25 (D. Mass. 2006), *aff'd in relevant part,* 507 F.3d 720 (1st Cir. 2007) (dismissing FCA complaint in its entirety because "[a]s all of Plaintiff's state claims allege fraud under statutes similar to the FCA, the requirements of Rule 9(b) apply equally to Plaintiff's state claims"); *Hopper v. Solvay Pharma., Inc.*, 590 F. Supp. 2d 1352, 1363 (M.D. Fla. 2008) (dismissing state law false claims counts because "in order to proceed in federal court, the state law claims would have to satisfy Rule 9(b)'s requirements, and, for the same reason that the federal claim [was] deficient under that rule, the state law claims [were] deficient as well"), *aff'd*, 588 F.3d 1318 (11th Cir. 2009).

after apparently conducting an extensive investigation, interviewing prescribing doctors and unnamed witnesses, and hiring a research organization to compile data and perform statistical analyses, Plaintiff has not pleaded facts sufficient to support the fundamental elements of his false claims counts. As such, his claims should be dismissed, this time with prejudice.

CONCLUSION

For all the foregoing reasons, Plaintiff's false claims counts (Counts I and III through XIX) should be dismissed with prejudice.

Date: June 18, 2010
New York, New York

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